

REMARKS

The Applicants wish to thank the Examiner for his examination of the present application. Claims 1, 3-6, 9, 11-18, 21, 25, 26, 29, 33, 38, 41-63, and 65-76 are currently pending in the application. Claims 1, 9, 11, 12, 18, 25, 26, 38, 42, 46, 52, 53, 63, 67, 68, 72 and 73 have been amended.

35 U.S.C. §101

The Examiner has rejected all of the pending claims (claims 1, 3-6, 9, 11-18, 21, 25, 26, 29, 33, 38, 41-63, and 65-76) pursuant to 35 U.S.C. §101 as directed to unpatentable subject matter in light of the newly developed interim guidelines for such rejections. Specifically, the Office Action cites Supreme Court precedent and recent Federal Circuit decisions as indicating that a statutory "process" under 35 U.S.C. 101 must (1) be tied to a machine or (2) transform underlying subject matter (such as an article or material) to a different state or thing, and states that Applicants claims do not meet these criteria. The Examiner states that the claimed methods "neither transform underlying subject matter nor positively tie to a machine that accomplishes the claimed method steps."

Applicants believe that, under the newly developed guidelines and the applicable case law, the claims in their prior form were directed to patentable subject matter. Regardless, they have amended claims 1, 9, 11, 12, 18, 25, 26, 38, 42, 46, 52, 53, 63, 67, 68, 72 and 73 to more clearly comply with the interim guidelines and the applicable law. The remaining pending claims are patentable for the same reasons, because they depend from one or more of the currently amended claims. Thus, Applicants submit that all of the claims are now in allowable form.

35 U.S.C. §101 states, “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.” In interpreting that law, the Supreme Court has reflected that “Congress intended statutory subject matter to ‘include anything under the sun that is made by man.’” *Diamond v. Diehr*, 450 U.S. 175, 182 (1981). The Court went on to reason:

That a process may be patentable, irrespective of the particular form of the instrumentalities used, cannot be disputed. ...A process is a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject matter to be transformed and reduced to a different state or thing. If new and useful, it is just as patentable as is a piece of machinery.

Diamond v. Diehr, 450 U.S. 175, 182-184 (1981) (citing *Cochrane v. Deener*, 94 U.S. 780, 787-788 (1877) (emphasis added)).

Applicants have amended the claims to ensure that both aspects of the test for statutory subject matter cited by the examiner are met. In other words, as amended, all of the claims are “new and useful” processes that (1) are tied to a machine in the form of a computer processing system, and (2) transform the underlying subject matter (e.g., transform data representing images of a body part into resultant boundary image data of the body part (as in claim 1), transform image data into an implant shape derived from the data (as in claim 38), and transform the image data into an actual implant that is manufactured (as in claim 67)).

Each independent claim as amended is directed to patentable subject matter. Amended claim 1 meets both prongs of the test for patentability cited by the Examiner for at least two reasons. First, claim 1 is a method of processing medical image data

using a computer processing system, and is thus tied to patentable subject matter. The elements of claim 1 make clear that this is not merely an abstract idea or mental exercise, but that a transformation of image data is performed by a computer processing system. Such computer systems are described throughout the specification, including at paragraphs 18, 83 and 91-99, which, among other things, describes the computer software code that could be used to program some embodiments.

Second, claim 1 requires that at least two images be transformed by combining boundary image data from these images to “form” a resultant boundary data volume that is distinct from the original images. As such, claim 1 claims “a series of acts, performed upon the subject matter to be transformed and reduced to a different state or thing” as required by Supreme Court precedent.

All of the other pending independent claims (claims 11, 18, 25, 26, 38, 52, 63, 67, and 72) also have been amended to ensure that they are similarly directed to patentable subject matter. As with claim 1, they are all tied to a machine and similarly include steps that require “using a computer processing system.” Thus, each of these claims is not directed to merely an abstract idea or mental steps, and, instead, each is tied to a machine that transforms the image data. Similarly, as with claim 1, each of these claims also includes the transforming steps of “extracting boundary image data” and “combining the extracted boundary image data.” In each case, the result of the claimed methods is one of “a resultant boundary data volume”, “a resultant data volume” or “a resultant image data volume.”

Furthermore, most of the independent claims require additional steps that further transform the resultant data. In the case of independent claims 11, 25, 38 63, 67 and 72, an implant shape is derived or selected based on the resultant data. In the case

of independent claims 18 and 26, a therapy is derived or selected based on the resultant data.

Thus, all of the amended claims are both tied to a machine and transform the claimed subject matter to a different thing. Therefore these claims are properly drawn to patentable subject matter under 35 U.S.C. § 101 and the associated case law. The remaining pending claims are similarly patentable for at least the same reasons, because they depend from at least one of the amended claims, and thereby incorporate the same elements.

CONCLUSION

It is submitted that all pending claims are in condition for allowance. Reconsideration of the claims and a notice of allowance are therefore requested.

It is believed that a three month extension of time is required. Applicants respectfully petition for such an extension. Authorization is hereby given to charge deposit account number 19-4972. If any additional fees are required for the timely consideration of this application, please charge deposit account number 19-4972.

Applicants request that the undersigned, Alexander J. Smolenski, Jr., be contacted if it will assist further examination of this application.

Respectfully submitted,

/Alexander J. Smolenski, Jr., #47,953/

Alexander J. Smolenski, Jr.
Registration No. 47,953
Attorney for Applicants

Sunstein Kann Murphy & Timbers LLP
125 Summer Street
Boston, MA 02110-1618
(617) 443-9292

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